K124043

Section 11 510(k) Summary or Statement

510(K) Summary

This is 510(K) summary in accordance with CFR807.82(c).

SEP 2 6 2013

A. Submitter Information:

Submitter: LightMed Corporation

Address: NO.1-1, Lane1, Pao-An St. Sec. 3,
Shulin Dist., New Taipei City 23861, Taiwan

Owner/ Operation Number: Mr. Gary Lee, President / 9040850

Contact person in Taiwan: Jocelyn Liu, Regulatory Affairs Officer

TEL: +886-2-2688-1726

FAX: +886-2-2676-4920

B. Device Name

Product Name: LightLas577/670 Multi-Wavelength Medical Laser System

Common Name: Ophthalmic Laser, Surgical Laser

Classification Name: 86 HQF, Laser, Ophthalmic

Regulation Name: 21 CFR 886.4390, Ophthalmic Laser

Regulatory Class: II

Performance standards: 21 CFR 1040.10 & 1040.11

C. Device Technological Characteristics to Predicate Device:

Manufacturer	LightMed Corporation LightLas532/670	LightMed Corporation LightLas577/670
510K Number	K103547	
Lasing Medium	Frequency doubled Nd:YAG/Diode	Semiconductor/Diode
Pulsing System	Continuous	Continuous
Output Wavelength	532nm/670nm	577nm/670nm
Micro Pulse	-	10% Duty Cycle (Power"On" 200μs, Power"Off" 1800μs

		from 0.01s~Continuous Wave for 577 nm only
Average Power(AP)	2W/0.7W	2W/0.7W
Laser Safety Class	4/IV	4/IV
Exposure Sections (t)	0.01s to continuous	0.01s to continuous
Cooling Method	Solid State Cooling with thermoelectric (Peltier) heat pump	Solid State Cooling with thermoelectric (Peltier) heat pump
Aiming Beam:	Coaxial with treatment beam	
Aiming Beam: Type	Red Laser Diode	Red Laser Diode
Aiming Beam: Wavelength	635-650nm (Red)	635-650nm (Red)
Aiming Laser power	Maximum of 1.0mW	Maximum of 1.0mW
Laser Safety Class	2/II	2/II
Power requirements: Voltage	100 to 240 Vac	100 to 240 Vac

D. Device Description

LightLas577/670 Multi-Wavelength Medical Laser System consists of a Laser Console where the Laser is housed along with the Electronic Control system and Power Supplies and various Laser Delivery Units (LDU's).

The LDU's include:

- Slitlamp Integrated into CSO model SL980. (K992836)
- Slitlamp Attachment for CSO model SL990 (K992836) and other Haag Streit clones.
- Slitlamp Attachment for Zeiss model SL30 Slitlamp (K862004)
- Laser Indirect Ophthalmoscope (LIO) using a Heine Omega 500. (K123316)
- Laser Indirect Ophthalmoscope (LIO) using a Keeler All pupil II (K854244)
- Endophotocoagulation Handpieces (K122905)

The LightLas 577/670 Multi-Wavelength Medical Laser System may be used at either the 577 nm wavelength or the 670 nm wavelength. The 577 nm wavelength source can be delivered through both output ports (Ports 1 and 2) of the laser console, while the 670 nm wavelength source is delivered through Port 1 only. Users may choose either wavelength from a LCD touch screen, and only one output port and one wavelength may be selected for use at a time. Laser wavelength selection of the system is indicated on the panel and controlled by system software.

E. Intended Use:

LightLas577/670 Multi-Wavelength Medical Laser System is an ophthalmic laser

instrument intended for use by ophthalmologists. The 577 nm wavelength laser is indicated for retinal and pan-retinal photocoagulation, endophotocoagulation, macular photocoagulation to treat leaking vessels, and laser trabeculoplasty. The 670 nm wavelength laser is indicated for retinal and pan-retinal photocoagulation.
The intended use has not changed from the predicate device (K103547)

F. Substantial Equivalence

LightLas577/670 Multi-Wavelength Medical Laser System has the same intend use, general design and fundamental scientific technology as the predicate device (K103547).Also the operating controls and functions are equivalent to the product. They have the same functional elements such as treatment wavelengths, treatment power, spot size and cooling system. Control systems such as the door interlock, and the safety systems and displays are constantly monitored in these systems for user intervention during a procedure or maintenance.

The difference in specifications of LightLas577/670 and LightLas532/670 (K103547) is that LightLas577/670 is based upon LightLas532/670 (K103547) with a modification of laser sources and corresponded control boards which causes different laser outputs. LightMed Corporation has demonstrated by evaluation of LightLas577/670 that modifications to current predicate devices are effective and safe.

There are no new hazards introduced by the Laser System as compared with the predicate devices.

G. Performance Data:

LightLas577/670 Multi-Wavelength Medical Laser System was evaluated according to the requirements of FDA recognized consensus standards (IEC60601-1, IEC60601-1-1, IEC60601-1-2, IEC60825-1, IEC60601-1-4, IEC60601-2-22 and ISO14971).These tests and evaluations were performed at LightMed facility and at outside test facilities as required.

Bench testing performance was completed, including the assembly, testing calibration and alignment of LightLas577/670 laser console and laser delivery units. All test results demonstrated that performance of LightLas577/670 Multi-Wavelength Medical Laser System complies with specifications and requirements.

The conclusions drawn from the performance testing of the LightLas 577/670 Multi-Wavelength Medical Laser System demonstrate that the device is as safe, as effective, and performs as well as the legally marketed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 26, 2013

Lightmed Corporation
Ms. Jocelyn Liu
Regulatory Affairs Coordinator
No. 1-1, Lane 1, Pao-An St. Sec. 3,
Shulin District, New Taipei City 23861, Taiwan

Re: K124043
Trade/Device Name: LightLas 577/670 Multi-Wavelength Medical Laser System
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: Class II
Product Code: HQF
Dated: August 16, 2013
Received: August 23, 2013

Dear Ms. Liu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Deborah L. Falls -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement as Requested by FDA

510(K) Number (if Known): K124043

Product Name: LightLas577/670 Multi-Wavelength Medical Laser System

Trade Name: LightLas 577/670

Indications for Use:

LightLas 577/670 is an ophthalmic laser instrument intended for use by ophthalmologists. The 577 nm wavelength laser is indicated for retinal and pan-retinal photocoagulation, endophotocoagulation, macular photocoagulation to treat leaking vessels, and laser trabeculoplasty. The 670 nm wavelength laser is indicated for retinal and pan-retinal photocoagulation.

The intended use has not changed from the predicate devices (K103547)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDR, Office of Device Evaluation (ODE)

Prescription Use: X OR Over-The-Counter Use:

(Per 21 CFR 801.109)

Charles Chiang -S
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(Division Sign-Off)
Division of Ophthalmic and Ear, Nose
and Throat Devices
510(k) Number K124043